

IACUC Protocol – New Amendment

Protocol Amendments may only be created on records that are currently in “Active” status.

► Create New Amendment

 NOTE: The CoeusLite Launch Page may be found at:
<https://coeus.itap.purdue.edu/coeus/userAuthAction.do>

1. Log-in to CoeusLite
2. Click “My IACUC Protocols”
3. Click the “Create New Amendment” button in bottom section of the IACUC Home page
4. Pop up window will open with all Active protocols listed; click the protocol you wish to Amend.

► To Add Personnel ONLY

 NOTE: In order to be added to a protocol, the personnel in question MUST be fully trained and able to work unsupervised. Their Animal Qualifications in the online database must reflect this. The database address is <https://engineering.purdue.edu/VPR/LAP/ptUsers>.

1. **Amendment Summary Text Field:** Enter a brief summary of what you are changing in your protocol. This makes it easy for the reviewers to pinpoint what is being amended.
2. **Check Boxes:** Check the boxes of ONLY the areas you are going to modify as described in the Amendment Summary. Since you are adding personnel, please check TWO BOXES: “Investigators/Study Personnel” and “Add/Modify Attachments”.
3. There will be two steps involved in adding personnel –
 - A. Add new personnel to the “Investigators/Study Personnel” tab in Coeus. Click on “Investigators/Study Personnel” in left navigation menu (under General Info). Add new personnel after searching and selecting their name. If a person is not able to be found – see **Troubleshooting** (below). Select appropriate roles and click Save.
 - B. Find the most recently approved version of your “**Protocol Application**” attachment form. This can be found on the Attachments screen, with the document type “Protocol Application”, if the latest approved was for your Initial application or a Triennia Renewal application –OR- it could have the document type of “Amendment Attachment” if you have had any amendments approved between Initial/Triennial submissions. Be sure to view and save this document to your desktop, as you cannot modify documents within the Coeus system. Add your new personnel to section 2.1 of the form, including their Q number & duties they will be performing on the protocol. ***Highlight ALL changes made via this amendment in YELLOW***. Once you are finished with your modifications to the form, save to your computer. Then, attach the amended form to the record – go to “Attachments” in the left navigation menu, and select the “Amend” link, to the right of

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the latest “Protocol Application” document. Browse and upload your new amendment attachment.

4. **Submit to IACUC** (See below)

➤ **To Add New Procedures or Procedures & Personnel**

1. **Amendment Summary Text Field:** Please enter a brief summary of what you are changing in your protocol. This makes it easy for the reviewers to pinpoint what is being amended, and also makes it easy to refer to a specific amendment in Coeus, as you can search the amendment summaries in ‘My IACUC Protocols’ / ‘Amendments and Renewals’ .
2. **Check Boxes:** Check the boxes of ONLY the areas you are going to modify as described in the Amendment Summary. To add procedures, you must attach a revised **“Protocol Application”** form, so always check **“Add/Modify Attachments”**, as well as any other sections you need to amend. If you are adding personnel along with your procedure changes, please see the previous instructions on how to add personnel.
3. **Protocol Details:** Go to each screen that corresponds to the box(es) checked on the Amendment Summary screen and make the described modifications directly to the appropriate data fields.
4. Find the most recently approved version of your **“Protocol Application”** attachment form. This can be found on the Attachments screen with the document type “Protocol Application”, if the latest approved was for your Initial application or a Triennial Renewal application –OR- it could have the document type of “Amendment Attachment” if you have had any amendments approved between Initial/Triennial submissions. Be sure to view and save this document to your desktop, as you cannot modify documents within the Coeus system. Add your new personnel to section 2.1 of the form (if applicable), including their Q number & duties they will be performing on the protocol. ***Highlight ALL changes made via this amendment in YELLOW***. Make necessary revisions to Procedures on the form, if applicable. Once you are finished with your changes to the form, save to your computer. Then, attach the amended form to the record – go to “Attachments” in the left navigation menu, and select “Amend” link, to the right of the latest “Protocol Application” document. Browse and upload your new amendment attachment.

 **IMPORTANT:** If you are modifying an existing attachment, be sure to click “Amend” to the right of the attachment you are modifying. Be sure to **highlight** your changes in the document before completing the Browse/Upload process. **NOTE: If you have previously highlighted this document for approved amendments or revisions, please make sure you remove the old highlighted sections so that PACUC can tell what you are adding with the current amendment.** This way, PACUC Reviewers will know exactly what has changed.

➤ **Troubleshooting**

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- ❖ **Cannot find personnel in “Investigators/Study Personnel” search results:** Usually this is because someone is new to the University or they are an undergraduate who is not in the Purdue employee database (Coeus pulls from the HR/Payroll database). The solution is to have them ADDED to Coeus.
 1. Go to ‘**Coeus Home**’ (upper left corner of the page). On the left menu you will see “**User Access Request Form**”.
 2. Complete and submit the form.
 3. Technical support will send you an email once the person has been added to the database.
 4. You may then add them to the ‘**Investigators/Study Personnel**’ section of your protocol.
- ❖ **No option to add a new attachment:** Be sure the “**Add/Modify Attachments**” check box (on the Amendment Summary screen) is checked and you have saved the Amendment Summary screen.
- ❖ **Cannot submit to IACUC:** Sometimes this occurs because the record is locked.
 1. Go to ‘**Coeus Home**’ (upper left corner of your CoeusLite screen)
 2. Select ‘**Current Locks**’ (upper right hand corner).
 3. If locked, select ‘Remove’ next to the locked record.

 **NOTE:** NEVER click on ‘Current Locks’ while you are still in the record ~ this will require your record to be unlocked by technical staff before you can move forward. **ALWAYS** go to Coeus Home first.

Submit to IACUC

 **NOTE:** Submission for both Academic Approvals and PACUC review are done electronically through the system. Only complete the “Submit to IACUC” function when the protocol is complete and ready for review.

1. Click “Submit to IACUC” in the left navigation
2. Click “Submit for Review”
3. Validation checks will automatically run. “Errors” MUST be corrected prior to submission. “Warnings” may be corrected if desired.
4. Click “Ok” and complete the following fields:
 - a. Type: select “Amendment”
 - b. Review Type: select “Pending IACUC Determination”
 - c. Type Qualifier: DO NOT USE
5. Click “Submit”
6. Click “OK” in confirmation window

PI Approval

 **NOTE:** The PI will be the first electronic Approval required. This allows for a delegate to complete the record entry while ensuring the PI is aware and authorizes the submission.

If PI completed record and has “Submitted to IACUC”:



1. Click “Return to IACUC Protocol”
2. Click “Approval Routing” in the left navigation
3. Click “Approve”
4. Enter Comments and/or Attachments if desired
5. Click “Approve” again to complete PI Approval

If Investigator Delegate completed record and has “Submitted to IACUC”:

1. Open record from “My IACUC Protocols” or Email Notification
2. Click “Protocol Details” and review submission
3. Click “Approval Routing” in the left navigation
4. Click “Approve”
5. Enter Comments and/or Attachments if desired
6. Click “Approve” again to complete PI Approval